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QUOTED. June 4, 2018. Laureen Geniusz.

by

US FDA investigator Laureen Geniusz said some device-makers aren't considering post-market data when determining whether their human factors work is complete and accurate. See what she said about usability here.

"Remember, firms also need to consider complaints and suggestions. Suggestions may not be complaints. They're feedback, inquiries, or whatever – but it can suggest that they're not happy or understanding your product. We see a lot of times that user feedback is kind of downplayed or minimized, and this can cause costly consequences later during recalls or other issues." Laureen Geniusz, investigator, US FDA

- Find out more: [Compliance Corner: FDA Investigator Lists 7 Common Human Factors Problems, Says Usability Is 'Overlooked'](#)

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